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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,528	01/20/2004	Ofer Binah	85189-6000	2981

28765 7590 05/09/2006

WINSTON & STRAWN LLP
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,528	BINAH ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *22-25 and 28-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Binah et al.

Election/Restrictions

The Election filed on February 21, 2006 in response to the Restriction Requirement of 1/23/2006 has been entered. Applicant's election of Group I, claims 1-21 and 26-27, as specifically drawn to an anti-tumor agent derived from reptile serum, comprising at least one serum protein from normal reptile serum has been acknowledged.

Applicants election of Group I, with traverse is acknowledged. However, it is noted that Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement. Therefore, the restriction requirement is deemed to be proper and is made FINAL.

Claims 1-35 are currently pending.

Claims 22-25 and 28-35 have been withdrawn from consideration as being drawn to non-elected inventions.

Claims 1-21 and 26-27 are currently under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 8/06/2004 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 and 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of reptile derived anti-tumor agents

comprising at least one reptile serum protein and/or an immunoglobulin, wherein the protein has a molecular weight in excess of 100,000 Daltons or 150,000 Daltons in its native form and a genus of anticancer agents comprising at least two proteins having a molecular weight of about 100,000 Daltons and a second protein having a molecular weight in excess of 200,000 Daltons, or a first protein having a molecular weight in excess of 150,000 Daltons and a second protein having a molecular weight in excess of 700,000 Daltons. Therefore, the claims encompass a genus of proteins defined solely by its principal biological property and approximate molecular weights, which is simply a wish to know the identity of any material with that biological property.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 2, lines 21-23) that the agents of the invention include polypeptides found in the serum of normal healthy alligators or crocodiles, characterized in that they show anti-tumor activity. For example, the specification teaches (page 16, lines 20+) that alligator serum was screened for anti-tumor activity in human tumor cell lines. Specifically, the specification teaches that based on size exclusion chromatography, it appears that the anti-tumor activity resides in a protein or proteins having a molecular weight of approximately 150,000 Daltons (page 8, lines 10-12). Specifically, the specification teaches that electrophoresis under denaturing conditions of fractions 11-12 and 13-14 which contain the anti-activity, provided two bands with anti-tumor activity, one approximately 67 kD and the second of approximately 30 kD. In addition, the specification teaches that it is clear that Serum Y, e.g., alligator serum, contains at least two factors, one factor having a molecular weight of about 150 kDa and a second having a molecular weight of about 700 kDa, that act in concert in order to exert the tumor cell killing effect (page 21, lines 15-17). Thus while the specification attempts to describe possession of a protein and/or fragments thereof in terms of function and molecular weight, there is insufficient written description

encompassing a "antitumor agent derived from reptile serum comprising at least one serum protein from normal reptile serum" because the relevant identifying characteristics of the genus such as structure or other physical and/or chemical characteristics of a "anti-tumor agent" are not set forth in the specification as-filed, commensurate in scope with the claimed invention. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of proteins derived from normal reptile serum that encompass the genus of anti-tumor agents nor does it provide a description of structural features that are common to the anti-tumor agents. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of anti-tumor agents, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Moreover, a lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international

application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 9-10, 13-14, 17-18, 21 and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Aizawa et al. (Nihon Univ. J. Med. 1964; 6: 97-110).

Aizawa et al. teach the cytotoxicities of snake serum. Specifically, the reference teaches the fractionation of at least two proteins from snake serum (page 101, Fig. 3). Moreover, the reference teaches that the snake serum has been shown to be cytotoxic to ascites tumor cells of various types and of different origins (page 89, paragraph bridging page 97 and 98). Thus, while Aizawa et al. do not specifically teach a "pharmaceutical composition" comprising the snake serum protein, the claims do not appear to recite any additional ingredients, such as a pharmaceutical carrier, which are present in addition to the reptile serum protein. As such, Aizawa et al. meets the claims limitation. Moreover, although Aizawa et al. does not specifically characterize the snake serum protein as a diagnostic agent, the intended use of the compound must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A composition is a composition irrespective of what its intended use is. See In re Tuominen, 213 USPQ 89 (CCPA 1982) Lastly, even though the product-by-process claim of Claim 26 is limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claims 1-4, 8-21 and 26-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Salceda et al. (US 2002/0127237, 2000) as evidenced by Cruse, J.M. and Lewis, R.E. (Illustrated Dictionary of Immunology; New York, 1995, pages 157-158).

Salceda et al. teach non-mammalian polypeptides, as well as naturally occurring antibodies, derived from reptiles (page 25, paragraph 0229 and page 29, paragraph 0274). Specifically, the PG publication teaches that the polypeptides, as well as naturally occurring IgG antibodies, are obtained from egg laying reptiles such as alligators (page 30, paragraph 0278). Moreover, Salceda et al. provides pharmaceutical compositions comprising the polypeptides or antibodies, which may be

used for the diagnosis, monitoring, staging, imaging and treating prostate cancer (abstract and page 39, paragraph 0389). Lastly, the PG publication teaches that the proteins and/or antibodies are isolated from the serum (page 36, paragraph 0359). Thus, even though the product-by-process claim of Claim 26 is limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) Moreover, while Salceda et al. do not specifically teach that the IgG antibody has a molecular weight of about 150,000 daltons, the claimed limitation would be an inherent property of the prior art's antibody because Cruse, J.M. and Lewis, R.E. teach that IgG antibodies have a molecule wt of 154 kD (page 157, 2nd column, *immunoglobulin G (IgG)*). Thus, the claimed immunoglobulin appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Therefore, No claim is allowed.

Conclusion

Claims 6-7 are rejected under USC 112, 1st paragraph written description, but appear to be free of the prior art. The closest prior art to claims 6-7 appears to be Salceda et al. (US 2002/0127237, 2000) as cited above. However, Salceda et al. do not teach or suggest that the serum protein from alligator serum has two proteins, wherein the first protein has a molecular weight in excess of 100,000 Daltons and a second protein has a molecular weight of about 200,000 Daltons. Therefore, Claims 6-7 appears to be free of the prior art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hoffman et al. (WO 99/17785, 1999) whom teach reptilian derived peptides for the treatment of microbial infections. Specifically, the reference teaches that the peptides are obtained from alligators.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER